



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

~~DOCUMENT CONTAINS CONFIDENTIAL BUSINESS INFORMATION~~

DP BARCODE No.: D442084; **FILE SYMBOL No.:** 83529-IN; **PRODUCT NAME:** Sharda Fluroxypyr MHE 26.2% EC; **DECISION No.:** 528490; **PC Code(s):** 128968; **ACTION CODE:** R300; **FOOD Use:** Yes

DATE OUT: August 17, 2017

SUBJECT: End Use Product Chemistry Review
Product Name: Sharda Fluroxypyr MHE 26.2% EC

FROM: Shyam Mathur, Ph. D
Chemistry Team Leader
Chemistry, Inerts & Toxicology Assessment Branch (CITAB) /RD (7505P)

TO: Bethany Benbow / Kathryn Montague, RM 23; Herbicide Branch / RD (7505P)

INTRODUCTION:

The registrant, Sharda USA, LLC, has submitted an application for the registration of the new end use product Sharda Fluroxypyr MHE 26.2% EC. The registrant has submitted a CSF for basic formulation (dated April 14, 2017) and the supporting product chemistry data with MRID Nos. 50247901 to 50247904. The registrant has claimed that the proposed product is substantially similar to the registered product with Reg. No. 71368-87. CITAB has been asked to determine the acceptability of the proposed basic CSF & the supporting product chemistry data and also determine similarity to the cited product.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s): Fluroxypyr 1-methylheptyl ester (MHE) (26.20%)
2. Has the registrant claimed substantial similarity to a registered product?

☒ Yes; ☐ No; ☐ NA; if yes give the registration number of the cited product EPA Reg.

Reg. No.: 71368-87
3. All of the source materials of the active ingredient are derived from registered sources- ☒ Yes ☐ No
4. All inert ingredients have been screened by CITAB (Inert group) and found to be approved for the proposed labeled uses: ☒ Yes; ☐ No

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5. Confidential Statement of Formula(s):

☒ Basic - Dated: 04-14-2017; Re-submitted - Dated: 08-17-2017

☐ Alternate CSF – All Dated: ; Re-submitted alt CSF – Dated:

Alternate CSF(s) complies with 40CFR§152.43: ☐ Yes; ☐ No; ☒ NA

6. Product label

- a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product label (PR Notice 91-2).

☒ Yes; ☐ No; if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredients)?

☒ Yes; ☐ No; if not, explain below:

Metallic equivalent: ☐ Yes ☒ NA

Soluble arsenic: ☐ Yes ☒ NA

Isomeric ratios: ☐ Yes ☒ NA

Acid Equivalent: ☒ Yes ☐ NA: Fluroxypyr acid equivalent = 1.6 lbs/gal or 18.5%

- b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☒ Yes ☐ No ☐ NA

Methanol at > 4%: ☐ Yes ☒ No ☐ NA

Sodium nitrate/Sodium nitrite ☐ Yes ☒ No ☐ NA

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- c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☐ Yes; ☒ No

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☐ Yes; ☐ No; ☒ NA; if not, explain below

- d. Label requires an additional Storage and Disposal statement:

☐ Yes; ☒ No; if yes explain below:

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7. Group **A**: Product Chemistry Data submitted

CITAB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		CITAB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	50247901
830.1600	Description of materials used to produce the product		X		A	50247901
830.1650	Description of formulation process		X		A	50247901
830.1670	Discussion on the formation of impurities		X		A	50247901
830.1700	Preliminary analysis			X	NA	
830.1750	Certified limits (158.350)	Standard certified limits	X		A	Revised Basic CSF dated 08-17-2017
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method		X		A	50247902

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable.

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8. Group **B**: Product chemistry data submitted

Guideline No.	Study Title	Value or Qualitative Description	CITAB's Assessment of Data	MRID Nos.
830.6303	Physical State	Liquid	A	50247902
830.6315	Flammability	Flash point = 75.5°C	A	50247903
830.6316	Explodability	Waiver request. Based on the flammability data, the TS is not potentially explosive	A	50247902
830.7000	pH	6.80 – 7.0 at 20.3°C (1% w/v)	A	50247902
830.7300	Density (units)	1.013 g/cc (8.44 lbs/gal) at 25°C	A	50247902
830.7100	Viscosity	10.20 cts @ 20°C 5.36 cts @ 40°C	A	50247902
830.6317	Storage stability	Stable for 2 weeks at 54°C when put in contact with Aluminum & Aluminum acetate, Lead & Lead acetate	A	50247902
830.6320	Corrosion characteristics	No corrosion observed when put in contact with Aluminum, Fe, Cu, Zn & Polyethylene (PE) for 2 weeks at 54°C	A	50247902
830.6314	Oxidation/reduction	Compatible with water, Fe, Zn, ammonium dihydrogen phosphate, ammonium dichromate, & calcium nitrate (tetra hydrate)	A	50247903

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The registrant has submitted the waiver requests for the following guidelines
(MRID No. 50247904)

Guideline No.	Title	Rationale for Waiver or Additional Information for Reference Guideline
830.6313	Stability to Normal and Elevated Temperatures, metals and ions	This product will not come into contact with metal containers or packaging. A storage stability and corrosion characteristics test was conducted at 54°C for two weeks and product was stable at test conditions. There were no changes in appearance of product or containers. <i>Reference: Storage Stability – 50287902</i>
830.6316	Explosibility	A flammability test was conducted and showed this product is not flammable; therefore it is requested that this data requirement be waived. <i>References: 40 CFR 158.310 Product chemistry data requirements table. MRID 50287903 (Flammability Study)</i>
830.6321	Dielectric breakdown voltage	This end use product does not have uses where the product would come into contact with electricity; therefore, it is requested that this requirement be waived. <i>Reference: 40 CFR 158.310 Product chemistry data requirements table.</i>
830.7050	UV/Visible Absorption	This is an end-use product formulation; therefore, these data are not required. <i>Reference: 40 CFR 158.310 Product chemistry data requirements table.</i>
830.7200	Melting Point	This is an end-use product formulation; therefore, these data are not required. <i>Reference: 40 CFR 158.310 Product chemistry data requirements table.</i>
830.7220	Boiling Point	This is an end-use product formulation; therefore, these data are not required. <i>Reference: 40 CFR 158.310 Product chemistry data requirements table.</i>
830.7370	Dissociation constant in water	This is an end-use product formulation; therefore, these data are not required. <i>Reference: 40 CFR 158.310 Product chemistry data requirements table.</i>
830.7520	Particle size, fiber diameter and particle distribution	This is an end-use product formulation; therefore, these data are not required. <i>Reference: 40 CFR 158.310 Product chemistry data requirements table.</i>
830.7550 830.7560 830.7570	Octanol Water Partition Coefficient	This is an end-use product formulation; therefore, these data are not required. <i>Reference: 40 CFR 158.310 Product chemistry data requirements table.</i>
830.7840 830.7860	Solubility in Water	This is an end-use product formulation, therefore these data are not required. <i>Reference: 40 CFR 158.310 Product chemistry data requirements table.</i>
830.7840 830.7860	Solubility in Organic Solvents	This is an end-use product formulation; therefore, these data are not required. <i>Reference: 40 CFR 158.310 Product chemistry data requirements table.</i>
830.7950	Vapor Pressure	This is an end-use product formulation; therefore, these data are not required. <i>Reference: 40 CFR 158.310 Product chemistry data requirements table.</i>

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CONCLUSIONS:

CITAB has reviewed the product chemistry data submitted for the end-use product and has concluded that:

A. Substantial similarity to the cited product (Reg. No. 71368-87) from Product chemistry view point

- ☒ Similar
☐ Not similar, give reasons:
☐ Identical
☐ Not identical
☐ Not applicable

B. Confidential Statement of formula

1. Basic CSF (dated: 08-17-2017)

- ☒ Acceptable
☐ Not Acceptable:
☐ Not Applicable

2. Alternate (dated:)

- ☐ Acceptable
☐ Not Acceptable:
☒ Not Applicable

C. Group A Product Chemistry Data

- ☒ Acceptable
☐ Acceptable with the exception of the guideline:
☐ Not acceptable
☐ Not required
☐ Data cited

D. Group B Product chemistry data

- ☒ Acceptable
☐ Not acceptable
☐ Acceptable with the exception of the guidelines
☐ Not required
☐ Data cited
☒ Waiver requests – ☒ Acceptable; ☐ Not Acceptable, ☐ Not applicable

E. Product Label/Draft Label: Recommendations – Yes []; No [X]